REMARKS

Attached hereto is a Request for an Extension of Time and the appropriate fee. The Office Action indicated that Claims 8 and 9 were indefinite under the second paragraph of 35 U.S.C. Section 112. Applicant wishes to thank the Examiner for the courtesy of pointing out these issues. These claims have now been accordingly amended.

Additionally, Claim 10 has been cancelled and it is believed that this removes the double patenting rejection under 35 U.S.C. Section 101.

The Office Action indicated that Claims 9-12 were rejected under 35 U.S.C. Section 101 as claiming the same invention as Claims 8-10 of the parent U.S. Patent No. 6,030,845.

Claim 8 included an additional step of calculating a plasma concentration with a hematocrit percentage. Thus, Claim 8 and the dependent Claims 9 and 10 of U.S. Patent No. 6,030,845 each has a calculating step. Our present Claims 9, 11 and 12 are missing the calculating step, and accordingly, it is believed that a double-patenting rejection is not proper.

Applicant wishes to accelerate the prosecution of this case and if the Examiner believes that an obviousness double patenting rejection over U.S. Patent No. 6,030,845 will be issued, applicant would request a telephone conference if this is the only remaining issue in the case so that a Terminal Disclaimer could be executed and hand carried directly to the Examiner.

Claim 8 was rejected as being obvious over the *Bradwell, et al.* U.S. Patent No. 4,889,815. As noted in the Office Action rejection, a nephelometer was utilized for analyzing the reactions of the whole blood and a second detector was needed to

near infrared range, nor does it even teach a wavelength with no hemoglobin absorption. With regards to the claim statement of no hemoglobin absorption, this is to be interpreted and understood with reference to our Fig. 5 that substantially no absorption is found that would interfere with our measurements as disclosed on the graph of Fig. 5.

Reference can be made with Fig. 2 of the *Bradwell, et al.* reference for a comparison with Fig. 5 of the present invention. As can be seen, the *Bradwell, et al.* reference only discloses a wavelength range from approximately 400 to 600 nm. In both of the charts of Figs. 2 and 5, the wavelength range centering around 400 nm shows absorption of radiation by proteins other than hemoglobin while a range of approximately 500 to 600 shows absorption by hemoglobin. As can be readily determined, *Bradwell, et al.* specifically selects a wavelength of about 480 nm to show a low absorption of hemoglobin. There is no teaching of considering a wavelength above 600 nm which is proposed and suggested in our present invention and shown in Fig. 5 of our present disclosure.

Additionally, the *Bradwell, et al.* disclosure is directed to a high degree of scattering and measures light at a 90° position as shown in Figs. 4, 5, 6 and 7. It should also be noted in Col. 2, Lines 2-11, that the lysed red cells are particularly prepared so that their fragments become particles of a size which does not scatter light in wavelengths between 460 and 510 nm. This teaching is further reinforced on Col. 3, Lines 1-15, wherein it is also pointed out that a high intensity light emitting diode at 480 nm could be used and thereby remove the necessity for filters.

In fact, the alternative embodiments of Figs. 1, 6 and 7 only disclose an on-axis detector that is used to time the duration of the light flash to particularly compensate for the absorption of hemoglobin.

In summary, it is quite clear that *Bradwell, et al.* teaches 480 nm wavelength and acknowledges that absorption by hemoglobin will occur and thereby compensates through a circuit which governs the duration of the light flash.

A person of ordinary skill in this field would certainly recognize that there is no teaching at any place in the embodiment of *Bradwell, et al.* that would suggest selecting a wavelength in the near infrared 800 nm range. Additionally, *Bradwell, et al.* specifically teaches the measurement of a scattering property and does not rely upon a measurement of absorption to determine the formation of an antigen-antibody complex or the amount of a protein in a sample.

As can be readily appreciated, the *Bradwell, et al.* reference not only did not teach nor disclose the use of radiation having a wavelength range which was substantially free from absorption from hemoglobin, but further did not teach that it was necessary for the hemolysis reagent to also not interfere with the absorption issue, for example, in Fig. 5 of the present application. Thus, the radiation wavelength picked and utilized in our present invention is substantially free from absorption by both hemoglobin and hemolysis reagent and these complimentary features are set forth in Claim 8. Accordingly, the language set forth in the means for measuring element reads upon the absorption range disclosed in Fig. 5 which can extend into the near infrared spectrum and will be significantly less than 0.5 so that light of this wavelength or within this wavelength range can be considered to

be free from absorption for purposes of the measurement used in our immunoassay system.

In light of the above amendments to the claims and the above comments, it is believed that the case is now in condition for allowance and early notification of the same is requested.

If the Examiner believes that the filing of a Terminal Disclaimer will accelerate the prosecution of this case, she is respectfully requested to contact the undersigned attorney by telephone at the listed telephone number.

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on January 26, 2001.

By: Daniel Kerby

Signature

Date: January 26, 2001

Respectfully submitted,

PRICE AND GESS

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